



Attorney Docket No.: 125889.101

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: :  
Fetterman et al. :  
Serial No. 10/722,262 : Group Art Unit: 1616  
Filed: November 25, 2003 : Examiner: Not Yet Assigned

For: METHOD OF ASSESSING AND MANAGING RISKS ASSOCIATED  
WITH A PHARMACEUTICAL PRODUCT

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
Mail Stop DD  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the provisions of 37 C.F.R. 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the documents listed on the attached form PTO-1449. Copies are provided. It is respectfully requested that the documents be expressly considered and that the documents be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

It is respectfully requested that the references be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

AUTHORIZATION

No fee is required. The Commissioner is hereby authorized to charge any additional fees which may be required for this submission, or credit any overpayment to deposit account no. 50-0436.

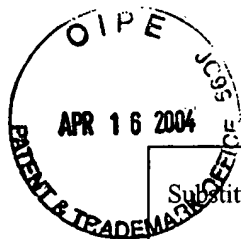
Respectfully submitted,

PEPPER HAMILTON LLP

A handwritten signature in black ink, reading "Raymond A. Miller". The signature is fluid and cursive, with the first name "Raymond" being more prominent than the last name "A. Miller".

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Date: April 14, 2004



Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>			
				<b>Application Number</b>	10/722,262		
				<b>Filing Date</b>	November 25, 2003		
				<b>First Named Inventor</b>	Fetterman		
				<b>Group Art Unit</b>	1616		
				<b>Examiner Name</b>	Not yet assigned		
<b>Sheet</b>	1	of 3		<b>Attorney Docket Number</b>	125889.101		
<b>U.S. PATENT DOCUMENTS</b>							
Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
		Number	Kind Code (if known)				
<b>FOREIGN PATENT DOCUMENTS</b>							
Examiner's Initials	Cite No.	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Office Number	Kind Code (if known)				
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
Examiner's Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or county where published.					T
	CA	White Paper: Supporting National Treatment Practice Guidelines by Combining CME Program and <i>Process of Care</i> ™ Approaches.					
	CB	DeRosier, Joseph; Stalhandske, Erik; Bagian, James P.; Nudell, Tina. "Using Health Care Failure Mode and Effect Analysis™: The VA National Center for Patient Safety's Prospective Risk Analysis System"; The Joint Commission May 2002 Journal.					

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

**CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.10**

**APPLICANT:** Fetterman et al.

**TITLE:** METHOD OF ASSESSING AND MANAGING RISKS  
ASSOCIATED WITH A PHARMACEUTICAL PRODUCT

**SERIAL NO.** 10/722,262

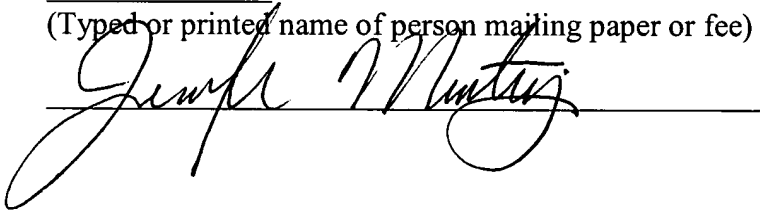
**ATTORNEY REF:** 125889.101

**DATE OF DEPOSIT:** April 14, 2004

I HEREBY CERTIFY THAT THIS INFORMATION DISCLOSURE STATEMENT WITH COPIES OF REFERENCES CITED THEREIN IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE VIA FIRST CLASS MAIL UNDER 37 CFR 1.10 ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO COMMISSIONER FOR PATENTS, MAIL STOP DD, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

Jennifer Martinez

(Typed or printed name of person mailing paper or fee)

A handwritten signature in cursive script, appearing to read "Jennifer Martinez", is written over a horizontal line.

Documents Enclosed:

1. Information Disclosure Statement with cited references;
2. Certificate of Mailing;
3. Postcard